Diana™ Hazardous Drug Compounding System Airflow Study
CEPA Operations, Inc. May, 2012

INTRODUCTION

Biological safety cabinets (BSCs) are designed to protect clinicians and the environment from exposure to vapors from hazardous chemicals. A Class II A/B3 BSC provides inward airflow, recirculating 70% of air through the cabinet’s supply HEPA filter and exhausting 30% of air through the exhaust HEPA filter. Any disturbances to airflow can affect the containment capabilities of the BSC.

PURPOSE

The Diana™ Hazardous Drug Compounding System (ICU Medical, Inc., San Clemente, CA) is a user-controlled automated compounding system for the safe preparation, reconstitution, and delivery of hazardous drugs that is designed to be used inside a pharmacy’s existing BSC. This comprehensive airflow pattern study was conducted in order to assess the impact of the Diana system on airflow patterns inside a BSC and determine whether the placement of the system has any impact on the BSC’s containment capabilities.

METHODS AND MATERIALS

To begin the test, the Diana system was placed in a Baker 4’ SterilGARD III Advance (model #SG403) Class II Type A/B3 BSC and connected (including all cables) to its printer, foot pedal, channel two diluent set, liquid sensor, channel one cassette, and IV bag tray. Medications, fluids, and patient IV containers were then connected and tested with the following ChemoClave™ adapters: CH-10, CH-33, CH-70, CH-74, and CH-80. Various large and small IV bags and syringes were also attached and evaluated.

RESULTS

Observations recorded during the study revealed the Diana system remained completely sealed during the test, and with no internal fan, the Diana itself caused no incremental disturbances to the airflow inside the BSC. Additionally, the slanted front touch screen allowed for smooth airflow down the front of the unit, and smoke rolled well over and around the main body of the unit. Uniform airflow up to and across all of the IV bags was also observed. The complete unit fit inside the 4’ BSC, and was slightly raised from the work surface, improving airflow. Minor rolling of smoke beneath the channel one IV bag tray was observed, but the smoke cleared within 3-4 seconds, even when a large IV bag (e.g., 1000 mL bag) was placed on the tray.

CONCLUSION

ICU Medical’s Diana system was observed to have minimal impact on and no adverse disruption of airflow inside the BSC. However, it is recommended that when the channel one IV bag tray is connected, the workspace directly underneath the tray be left clear, and that the tray be removed or tilted upwards when not in use.